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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kim A. Beazley

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HOWREY LLP

C/O IP DOCKETING DEPARTMENT

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/541,834	BEAZLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10, 13, 27 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 13, 27, 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group V, claim 13, in the reply filed on 4 February 2008 is acknowledged. The traversal is on the ground(s) that the invention of Group I represents a species of the invention of Group V. This is found persuasive.

The requirement is withdrawn between Groups I and V. The claims directed to the invention(s) of Groups II-IV and VI-XIII have been cancelled.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

### ***Claim Objections***

3. Claims 1 and 2 are objected to because of the following informalities:

Claim 1 should start with the article of language "A" because a claim should be limited to a single invention under 35 USC § 101.

Claim 2 should be amended to read -- An alfalfa plant --, because claim 1 is directed to a seed not a plant.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At line 3, the limitation “alfalfa event J-101” does not appear to be an art recognized designation for an alfalfa plant. The sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims. For example, the plant disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one’s ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed breeding line would obviate this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6, 10 and 35 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability.

(a) If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

(b) If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR §§ 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent in accordance with 37 CFR § 1.808(a)(2);
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

8. Claims 13, 27, 33 and 34 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for alfalfa plant J-101 representative seed deposited with ATCC with Accession No. PTA-4814 and progeny produced therefrom comprising event J101, does not reasonably provide enablement for any glyphosate tolerant alfalfa plant comprising SEQ ID NO: 1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim an alfalfa plant comprising a glyphosate tolerant trait genetically lined to a complement of a marker polynucleic acid comprising SEQ ID NO: 1 or 2.

Applicants teach alfalfa transformation event J-101 produced by transforming alfalfa line R2336 with transformation plasmid pMON20998 (page 18, lines 26-30 of the specification).

Applicants do not teach how to make and use a genus of alfalfa plants that are glyphosate tolerant and comprising SEQ ID NO: 1 or 2; or comprising SEQ ID NO: 3 and 4 (instant claim 33).

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The instant claims are directed to a transgenic, glyphosate tolerant alfalfa plant wherein there can be any transgene giving glyphosate tolerance genetically linked to SEQ ID NO: 1 or SEQ ID NO: 2. In the instant art, it is highly unpredictable in using homologous recombination to exchange specific genetic material from a different nucleic acid sequence at a specific genomic site. SEQ ID NO: 3 comprises alfalfa genomic sequences and FMV promoter sequence, SEQ ID NO: 4 comprises alfalfa genomic sequences and E9 terminator sequence. None of SEQ ID NOs 1-3 comprise nucleic acid sequences that produce glyphosate tolerance in a transgenic plant. Given that Applicants do not teach one skilled in the art how to produce a homologous recombination at the J-101 transformation site it would have required undue trial and error experimentation to make and use the invention as broadly claimed.

9. Claims 4-6, 13, 27 and 33-35 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim progeny of alfalfa plant designated J-101 comprising SEQ ID NO: 1-3. Applicants claim an alfalfa plant comprising a glyphosate tolerant trait genetically lined to a complement of a marker polynucleic acid comprising SEQ ID NO: 1 or 2.

Applicants describes alfalfa transformation event J-101 produced by transforming alfalfa line R2336 with transformation plasmid pMON20998 (page 18, lines 26-30 of the specification).

Applicants do not describe a genus of alfalfa plants that are glyphosate tolerant and comprising SEQ ID NO: 1 or 2; or comprising SEQ ID NO: 3 and 4 (instant claims 4 and 33).

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



11. Claims 4-6, 10, 13, 27 and 33-35 are rejected under 35 U.S.C. § 103(a) as being obvious over Fincher *et al* (U.S. Patent 6,462,258 B1, filed 15 December 2000, issued 8 October 2002).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. § 102(a) and (e).

Fincher *et al* teach pMON20998 (column 35, Table 5) which comprises the transformation insert of pMON10156 (Figure 12), and that alfalfa is a suitable target plant of interest for the nucleic acid constructs of the invention (column 14, lines 3-10).

Applicants teach alfalfa transformation event J-101 produced by transforming alfalfa line R2336 with transformation plasmid pMON20998 (page 18, lines 26-30 of the specification).

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the teachings of Fincher *et al* to transform an alfalfa plant with the pMON10156 transformation plasmid. As the instantly rejected claims are not limited to an alfalfa plant comprising the J-101 transformation event, the presence of SEQ ID NO: 1-4 would not have lead to a teaching of unexpected results. One of ordinary skill in the art at the time of Applicants' invention would have had a reasonable expectation of success in making a glyphosate tolerant alfalfa plant using the teachings of Fincher *et al*.

### **Conclusion**

12. No claims are allowed.

13. Claims 1-3 are free of the prior art which does not teach the alfalfa plant designated J-101 representative seed deposited with ATCC with Accession No. PTA-4814.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
21 July 2008